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(54) Wound dressings

(57) This invention relates to wound dressings and provides a dressing comprising a solid body of polymeric material of non-uniform thickness, preferably of crosslinked silicone.

In one embodiment of the invention, the body of material may be transparent and shaped so as to provide a magnified virtual image of an underlying wound. It may, in another embodiment, have a thickness which decreases substantially from the edges towards the centre, so as to allow pressure which may be applied to an underlying wound to be borne by areas surrounding the wound.

The drawing(s) originally filed was (were) informal and the print here reproduced is taken from a later filed formal copy.

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FIG. 1

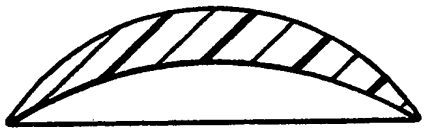

FIG. 2

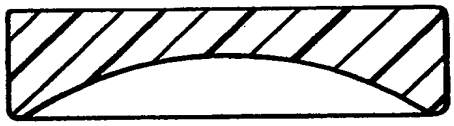

FIG. 3

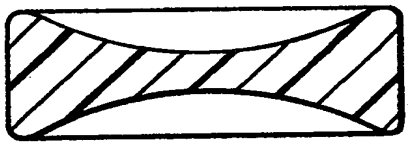

FIG. 4

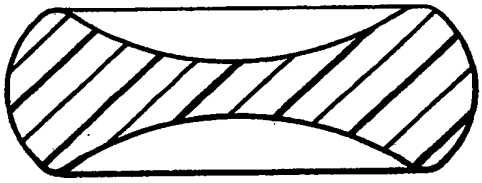

FIG. 5

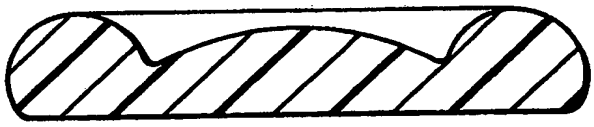

FIG. 6

WOUND DRESSINGS

This invention relates to wound dressings.

Wound dressings are known which comprise sheets of polymeric material. EP-A-0100148 describes a medical - surgical dressing comprising a reinforced sheet of silicone elastomer foam. That dressing is said to be useful for the treatment of wounds, burns and as liners for plaster casts. Silicone gel sheets (which, almost exclusively, are reinforced) have been successfully used in the management of burns, scalds, blisters, scars and decubitus ulcers. They have been proven to be efficacious in both the prevention of hypertrophic scarring (e.g. during the healing of a burn) and also in the reduction of established hypertrophic scarring. It is thought that their effectiveness at reducing scarring is a result of their rheological properties and the fact that they release low molecular weight methylsiloxane oils which may have a softening effect on skin and scar tissue.

According to the present invention, there is provided a wound dressing comprising a solid body of polymeric material of non-uniform thickness.

According to a first aspect of the invention, the dressing comprises a solid lenticular body of transparent polymer material shaped so as to provide a magnified virtual image of an underlying wound.

The body of polymer material according to the first aspect of the invention may be plano-convex or concavo-convex in shape.

The invention in its first aspect has the advantage that a wound beneath the dressing can not only be seen by the medical practitioner tending the patient, but indeed the wound is magnified by the dressing for improved visual monitoring. Furthermore, th dressing is less easy to dislodge than conventional dr ssings of ss ntially uniform thickness, because th r latively thick edges of

such conventional dressings can b accidentally caught and lifted. The lenticular shape also provides greater mechanical protection at the centre, where it lies over the wound.

Lenticular bodies for application to the skin have been proposed previously in the field of fluid-filled pressure pads. Thus, US-A-4202331 discloses a transparent bag filled with a liquid or a water-based gel as a means for applying pressure to a skin graft, and it is mentioned in passing that such a bag, when filled with a liquid silicone, may provide a degree of magnification of the graft tissue. Skin graft pressure pads, however, would not normally be considered to be wound dressings, and th y would have a number of significant drawbacks if used as wound dressings, as compared with the wound dressings of the present invention. For example, they could not be cut to size (a feature which is regarded as very important by many medical practitioners), they would not conform well to microscopic (as against macroscopic) skin contours, and there is a possibility that they might become dislodged, especially on ambulatory patients, as a result of the mobility of the liquid within the bag. Moreover, the manufacture of a fluid-filled bag is complicated, and therefore costly, by comparison with the manufacture of the solid dressings of the present invention.

In this first aspect of the present invention, the body may, for example, be approximately circular with an approximately spherical upper surface and a generally flat lower surface. The body will conveniently be from 1.0 to 15.0cm (preferably from 3.0 to 10.0cm) in diameter, and from 0.5 to 2.0 cm (preferably from 0.8 to 1.5cm) thick at its centre. The thickness at the circumference will preferably be less than 0.1cm.

Th optical power of the dressing (when in us , but undistorted) will g n rally be from 0 to 50 D, and pr ferably from +5 to +20 D. It will b appr ciated that

wh n th dressing is in use it constitutes a lens in surface-to-surface contact with its obj ct, and it therefore provides only one refracting surface. Accordingly, the optical properties of a dressing of the present invention, as determined by reference to the standard formulae for calculating the power of a spherical lens in air, are not representative of the true optical properties of the dressing in use. Moreover, the dressings of the present invention may be distorted in use to such an extent that their powers are increased or decreased by several dioptres. The effect of such distortion on the optical properties of flexible lenses is discussed by A.G. Bennett in Oplith. Opt. (1976), p939.

Preferably, the magnifying dressings of the present invention provide a degree of magnification of from 5% to 50% in use, and more usually from 8% to 20%.

The lenticular body may take a variety of shapes, not necessarily regular, and there may be only a portion that acts as a magnifying lens. The body surrounding such a magnifying portion may be reinforced, such as with a fibrous material.

According to a second aspect of the invention, the wound dressing comprises a body of polymer material having a thickness which decreases substantially from the edges thereof towards the centre.

The dressing according to the second aspect of the invention allows pressure which may be applied to the wound to be borne by areas surrounding the wound, rather than directly on the wound itself. Such a dressing may take any of a number of shapes, such as circular, oval or rectangular. Preferably the wound-contacting surface is generally flat so that the dressing combines the healing properti s of th silicone with the physical protection d scribed. Such a dressing has advantag s over known pads for r li ving pr ssur , in that the dressing is itself mould d into the requir d shape, thus being r lativ ly

simple to manufactur as a one-piece combined dressing and pressure-reli f pad.

Dressings according to the second aspect of the invention are particularly useful for dressing boney prominences such as heels, elbows or hips, tending to k ep pressure off the centre portion of the dressing which overlies the injury which it is desired to protect.

The dressing will generally be from 1.0 to 15.0 cm in diameter, and preferably from 3.0 to 10.0 cm in diameter. Around the periphery of the dressing, it will preferably be from 0.5 to 5.0 cm thick, more preferably from 0.8 to 3cm thick, and most preferably from 1.0 to 2.5cm thick. The minimum thickness of the dressing is preferably from 0.1 to 2.0 cm, more preferably from 0.2 to 1.0 cm, and most preferably from 0.3 to 0.8 cm. The edges of the dressing may be chamfered.

If desired, the dressing (or a central region thereof) may be transparent, thus allowing visual inspection of a wound to which it is applied. If made transparent, it will generally be of neutral optical power or it will be a slightly condensing lens (eg. having an optical power, when in use but undistorted, of from 0 to -10D.)

In either aspect of the invention, the polymer is preferably a crosslinked silicone. Among the advantages of crosslinked silicones is a high degree of conformability and deformability, not only on a "macro" scale, e.g. conforming to the part of the body in question, but also on a "micro" scale, e.g. conforming to microscopic undulations of the skin. Thus the conformance of the gel to the surface of the skin is such that surfac reflections and specular diffusion are greatly reduced, improving the image clarity. The view of a lesion through the gel dressing is thus likely to b cl ar r and appar ntly b tter d fined, wh n compared with th view through, say, a glass l ns that would conform less well to th surface.

In either aspect of the invention, the cross-linked silicon may be a tacky gel, or may be a non-tacky gel, or may comprise tacky and non-tacky surfaces.

Silicones are a group of completely synthetic polymers containing the recurring group $-SiR_2O-$ wherein R is a radical such as an alkyl, aryl, phenyl or vinyl group. The simpler silicones are oils of very low melting point, while at the other end of the scale of physical properties are highly crosslinked silicones which form rigid solids. Intermediate in physical properties between these two extremes are silicone elastomers such as gels and rubbers.

The crosslinked silicones which may be used in the dressings of the present invention can conveniently be characterised in terms of their tensile strength, penetrability and peel strength. As the term is used herein, "tensile strength" means the maximum tensile load which can be applied (by means of a standard Instron tester) to a 5 cm wide, 3 mm thick strip of the crosslinked silicone in question. "Penetrability" is the degree to which a standard 50 g brass probe will penetrat into the silicone under its own weight in 8 seconds. The probe is generally cylindrical, 5 mm in diameter, and has a part-spherical tip with a radius of curvature of 3.625 mm (i.e. the tip is a 1 mm thick segment of a sphere). "Peel strength" is the force required to peel one end of a 5 cm wide, 3 mm thick strip of the silicone from a flat stainless steel surface, with the force being applied normally to the surface.

Tacky gels may be used to form dressings according to the invention. These gels generally have a tensile strength of from 50 to 400 g, a penetrability of from 5 to 50 mm and a peel strength of from 5 to 100 g. Preferably, such gels have a tensile strength of from 80 to 300 g, a penetrability of from 8 to 30 mm and a peel strength of from 10 to 50 g. Particularly preferred tacky gels have a

tensile strength of from 100 to 200 g, a penetrability of from 10 to 25 mm (e.g. about 12 mm) and a peel strength of from 15 to 35 g (e.g. about 25 g).

The crosslinked silicones which may be used to form non-tacky dressings are preferably rather more robust than the above-described tacky gels. They may, for example, be silicone rubbers. If silicone gels are used, they may have a tensile strength of from 100 to 600 g, a penetrability of from 1 to 10 mm, and a peel strength of from 0 to 15 g. Preferably, the non-tacky silicones are gels having a tensile strength of from 200 to 400 g, a penetrability of from 2 to 8 mm and a peel strength of from 0 to 10 g. Particularly preferred are silicones having a tensile strength of from 260 to 330 g, a penetrability of from 4 to 7 mm and a peel strength of from 2 to 6 g (e.g. about 5 g).

The non-tacky silicones which may be used in the dressings of the present invention preferably display a Shore A hardness of less than 5, and more preferably less than 2. Particularly preferred are silicones having a Shore A hardness of less than 1, and most preferable are gels having no measurable Shore A hardness.

The crosslinked silicones may be formed from linear silicones having reactive groups thereon, as is known in the art. The reactive groups which cause the crosslinking reaction may be silanol groups. Such groups will react with other silanol groups in the presence of a suitable catalyst (such as stannous octoate) or heat, or both, with the elimination of water. Preferably, however, the gels are formed by reaction between a vinyl-substituted silicone and hydride-containing silicone in the presence of a suitable catalyst such as a platinum catalyst.

The starting silicones may have a number average molecular weight in the range 5000 to 200,000, and may, for example, have from 0.004 to 0.4 mmoles per active group/g. Preferably, the number average molecular weight

is from 10,000 to 100,000, and from 0.01 to 0.2 mmol s reactive group ar present /g of silicon s.

When the silicones are formed by crosslinking a mixture of two or more silicones, the molecular weights of the various components and/or their degree of substitution by reactive groups may be different. This allows gels having different physical properties to be formed merely by varying the proportions of the components.

For example, a tacky gel can be formed by using a relatively high proportion of high molecular weight, hydride-containing component and a relatively low proportion of a low molecular weight, vinyl-substituted component. The hyride-containing component may constitute from 50% to 90% by weight of the starting materials, and preferably from 60% to 80%, for example 70% by weight, th balance being the vinyl-substituted component. Such a gel is found to have a typical light transmittance in the visible region greater than 80% for a 10mm thickness. The actual value of the transmittance will depend as much on the quality of manufacture of the gel as on its inherent light transmittance. A transmittance in the visible region of 90% for a 10mm thickness is attainable without great difficulty. A silicone gel which is dry and non-tacky to the touch may be formed by using a relatively high proportion of the same vinyl-substituted component, and a lower proportion of the hydride-containing vinyl-substituted component. For example, such gels may be formed from mixtures containing from 50% to 90% by weight of the component, and preferably from 60% to 80%, for example 70% by weight, the balance being the hydride-containing component.

When two components of different molecular weight are employed, the larger molecular weight component preferably has a number average molecular w ight in th range 25,000 to 70,000, and it pr ferably has from 0.05 to 0.2 mmoles reactive group (e.g. hydrid groups) /g. More

preferably, the larg r molecular weight component has a number average mol cular weight in the range 40,000 to 45,000 (generally corresponding to a viscosity of from 1500 to 1700 mPas), and has from 0.07 to 0.13 mmoles reactive group/g.

The smaller molecular weight component preferably has a number average molecular weight in the range 10,000 to 25,000, and it preferably has from 0.01 to 0.025 mmoles reactive group (e.g. vinyl groups)/g. More preferably, the smaller molecular weight component has a number average molecular weight in the range 16,000 to 20,000 (generally corresponding to a viscosity of from 400 to 600 mPas), and has from 0.016 to 0.018 mmoles reactive group/g.

If the crosslinked silicones for use in the present invention are to be formed from vinyl-substituted and hydride-containing poly(dimethylsiloxanes), it is preferred that the hydride groups be present in at least a four-fold excess over the vinyl groups in a mixture of equal parts by weight of the starting materials.

The components for forming suitable crosslinked silicones for use in the dressings of the present invention are available from Bayer (UK) Limited, England, under the references VP AC 3293 (A) and VP AC 3293 (B). These are vinyl-substituted and hydride-containing poly(dimethylsiloxanes), respectively.

The dressings of the present invention may be formed by casting non-crosslinked silicone material into a suitable mould and then causing it to crosslink i.e. cure. In the case of gels formed by reacting vinyl groups of one component with hydride groups of the other component, such curing will generally be carried out in the presence of a catalyst such as a platinum complex at a concentration of from 5 to 15 ppm. In such a case, the gel may be cur d at room temp ratur over a period of several days, but elevat d temperatures ar pref rably

employed. For example, the silicon gels may be cured at a temperature of from 40° to 120°C and preferably at a temperature between 80° and 100°C. At a temperature of 80°C, curing will generally take from 10 seconds to 10 minutes, for example from 1 to 5 minutes. At a temperature of 50°, curing will generally take from 10 minutes to 2 hours, for example from 15 minutes to 1 hour.

When the dressing comprises crosslinked silicone, it may have tacky crosslinked silicone gel on its wound-contacting surface and non-tacky silicone gel on its opposite surface.

It will be understood that the dressing of the invention could be formed as a Fresnel lens, thereby giving the optical magnification required.

The dressings of the present invention are further illustrated by the following examples, with reference to the drawings, which show various dressings according to the invention, all in cross section, but not necessarily to scale.

EXAMPLE 1

A circular silicone gel patch is provided, as shown in cross-section in Figure 1, 6cm in diameter, with one plane surface and one spherical surface. The patch has a maximum thickness of 1.2cm, which corresponds to a radius of curvature of 4.36cm for the spherical surface. The silicone gel is formulated such that the plane side is tacky and able to adhere to a surface (e.g. skin). The tack of the plane surface is such that the peel strength is 25g. The patch weighs 18.7g and the gel has the following physical properties: penetrability 12mm, tensile strength 150g, refractive index 1.405, and a UV/visible light transmittance of greater than 90%.

The refractive index, combined with the good light transmittance, allows the patch to be used as a flexible

optical lens. When in contact with a flat surface it displays an optical power of +9.3 D, giving approximately 8% magnification.

A gel patch of the type described above might be made either by casting in a mould, or by injection-moulding techniques.

As a wound dressing, e.g. in the treatment or prophylaxis of scars, this type of patch would be useful for generally flat areas of the body, or those areas with large radii of curvature. Examples are chest walls, thighs, cheeks, etc. The patch is self-adhesive on the plane surface, but can be removed from the wound surface without significantly damaging it. In use, it may be further secured in place by taping or bandaging, if required. In particular, pressure bandaging might be used.

EXAMPLE 2

A circular silicone gel patch is provided, as shown in Figure 2, 6cm in diameter, with one convex spherical surface and one concave spherical surface. The patch has a maximum thickness of 0.6cm, which corresponds to a radius of curvature of 4.36cm for the inner spherical surface, and 3.40cm for the outer convex spherical surface. The gel is formulated such that both surfaces are non-tacky and will not adhere directly to non-smooth surfaces (e.g. skin). Typically, the patch will weigh 11.1g and the gel have the following physical properties: penetrability 6mm, tensile strength 300g, refractive index 1.405, and a UV/visible light transmittance of greater than 90%.

Although primarily intended as a wound management aid, the refractive index, combined with the good light transmittance allows the patch described above to be used as a flexible optical lens.

This typ of patch is useful as a wound dr ssing, e.g. in the treatment or prophylaxis of scars or pr ssure sores, for protruding areas of the body, such as elbows, heels or knees. The patch may be held in place by suitable bandaging or taping, and in particular by pressure bandaging.

EXAMPLE 3

A circular silicone gel patch is provided as shown in Figure 3, which is 6cm in diameter, with one plane surface and one concave spherical surface. When in use it is intended that the concave surface contacts the object. The patch has a minimum thickness of 0.6cm, and the concave surface a radius of curvature of 4.36cm. The gel is formulated such that the concave surface is tacky and able to adhere to a surface (e.g. skin). The tack of th concave surface is such that the peel strength is 25g. Typically, the gel will have the following physical properties: penetrability 12mm, tensile strength 150g, refractive index 1.405, and a UV/visible light transmittance of greater than 90%.

If the dressing is applied to a part of the body which has a radius of curvature generally corresponding to the radius of curvature of the concave surface of the dressing, the underlying wound will effectively be viewed through a plane surface, and the dressing will have little or no magnifying or condensing effect. However, the dressing will nonetheless afford an excellent view of the wound because of the very low specular diffusion at the objection surface.

The dressing is particularly useful in the treatment or prophylaxis of scars or pressure sores on protruding ar as of the body, such as lbows, knees or he ls. If n cessary, the patch may be further secured in place by suitabl taping or bandaging. Wher as the patch d scribed

in Example 2 would be most appropriate for us when the application of pressure to a lesion was desirable, the dressing of this Example would be most appropriate when trying to protect a lesion from pressure shocks and the like.

EXAMPLE 4

A circular silicone gel patch is provided as shown in Figure 4, which is 6cm in diameter, with two concave spherical surfaces. The patch has a minimum thickness of 0.3cm, and radii of curvature of 4.36cm. The gel is formulated such that one surface (the lower surface) is tacky, and the other surface (the upper surface) is non tacky. The lower tacky surface is intended to contact the skin and adhere to it. The upper surface will not adher directly to non-smooth surfaces, such as clothing. The gel patch will have a refractive index of 1.405 and a light transmitance of greater than 90%.

When placed in contact with a wound, the dressing acts as a weakly condensing lens (optical power - 9.3D), but nonetheless gives a clear view of the wound.

A gel patch of this type may be made in a two-step moulding process, e.g. by casting the lower half using a tacky gel and then casting the upper half onto this using a non-tacky gel.

This dressing, like that of Example 3, is particularly useful in the treatment or prophylaxis of pressure sores on protruding areas of the body, such as heels or elbows. If necessary, the patch may be further secured in place by suitable taping or bandaging.

Figures 5 and 6 show further possible profiles for a wound dressing according to the invention. Figure 5 is similar to Figur 4, but shows a dr ssing having a curved annular edg . Figur 6 shows a dressing having magnifying properti s in th centr but having a thick edge for r lieving pressure from the centre.

It will be appreciated that the various lenticular shapes of the dressings of the invention have advantages for differing medical uses. For example, a patient with a localised hypertrophic lesion, such as a small raised scar, may be treated with a silicone gel patch, combined with mild sustained pressure, in order to improve the appearance of the lesion and make it less hypertrophic. In this case a plano-convex shape as in Example 1 would be particularly useful, as the pressure profile generated would cause most pressure where it was needed (over the lesion), and least pressure where it was not needed (around the lesion).

For a patient with a localised decubitous ulcer, such as a small pressure sore, the lesion requires to be protected from the environment and also from excess pressure and pressure shocks. A case like this may be treated with a biconcave or plano-concave shaped gel dressing such as in Examples 3, 4, and 5. Here the pressure profile would be such that the greatest pressures were on the intact skin around the periphery, and the lowest pressures on the lesion. The dressing of Figure 6 would also be useful.

For a patient with a lesion on a body prominence, such as a heel, it would be difficult to make a flat sheet conform to the body surface without placing undue pressure on the lesion. In this case a plano-concave or biconcave shape, such as in Examples 3, 4 and 5, or the shape of Figure 6, is desirable.

Also, there are cases where a generally flat sheet, such as a Fresnel lens may be more medically advisable, for instance with a non-localised hypertrophic lesion, when a uniform pressure over a broad area could well be required.

It will, of cours , be understood that th above description has been given by way of xample only and the modifications of detail can be made with the scope of the invention.

CLAIMS

1. A wound dressing comprising a solid body of polymeric material, of non-uniform thickness.

2. A wound dressing according to claim 1, wherein the polymeric material is a crosslinked silicone.

3. A wound dressing according to claim 1 or claim 2 comprising a solid lenticular body of transparent polymeric material shaped so as to provide a magnified virtual image of an underlying wound.

4. A dressing according to claim 3 in which the body has a lens power, when undistorted and in contact with an object to be magnified, of between 0 and +50 Dioptres.

5. A dressing according to claim 4 wherein the power is between +5 and +20 Dioptres.

6. A dressing according to any one of claims 3 to 5 in which the body is formed as a Fresnel lens.

7. A dressing according to any of claims 3 to 6 comprising a magnifying portion of the body which is surrounded by a reinforced portion, which is reinforced with fibrous material.

8. A wound dressing according to claim 1 or claim 2 comprising a body of polymeric material having a thickness which decreases substantially from the edges thereof towards the centre.

9. A dressing according to any one of claims 1 to 8 wherein the polymeric material is a tacky crosslinked silicone gel.

10. A dressing according to claim 9 wherein the gel has a peel strength of from 5 to 100 g.

11. A dressing according to claim 9 or claim 10 wherein the gel has a tensile strength of from 50 to 400 g.

12. A dressing according to any of claims 9 to 11 wherein the gel has a penetrability of from 5 to 50 mm.

13. A dressing according to any one of claims 1 to 8 wherein the polymeric material is a non-tacky crosslinked silicone elastomer.

14. A dressing according to claim 13 wherein the elastomer has a peel strength of from 0 to 15 g.

15. A dressing according to claim 13 or claim 14 wherein the elastomer has a tensile strength of from 100 to 600 g.

16. A dressing according to any of claims 13 to 15 wherein the elastomer is a gel having a penetrability of from 1 to 10 mm.

17. A dressing according to any of claims 1 to 8 comprising tacky crosslinked silicone gel on one surface thereof and non-tacky crosslinked silicone elastomer on the opposite surface thereof.

18. A dressing according to claim 17 wherein the tacky silicone gel is as recited in any of claims 10 to 12 and the non-tacky silicone elastomer is as recited in any of claims 14 to 16.

19. A dressing substantially as hereinbefore described with reference to any one of the Examples or any one of Figures 1 to 6.

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